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EXAMINER	
NGUYEN, HUONG Q	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,339	VOEGELE, JAMES W.	
	Examiner	Art Unit	
	HELEN NGUYEN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7 and 21-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7 and 21-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 4/13/2009. Claims 1 and 21 are amended overcoming the previous claim objection. Claim 6 is cancelled. **Claims 1, 5, 7, and 21-34** remain pending and under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 1, 5, and 34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle et al (US Publication No. 2002/0120211) in view of Truckai et al (US Pat No. 6485436) or Shadduck (US Pat No. 6740082).

4. In regards to **Claim 1**, Wardle et al discloses a biopsy device comprising:

a hollow sleeve (14) adapted to receive a tissue piercing element (72) therein, the sleeve comprising an open proximal end, a distal end, a sidewall extending between the proximal end and the distal end, best seen in Figure 2B, and a tissue receiving opening (22, 26) disposed intermediate the proximal end and the distal end, wherein the tissue receiving opening is formed laterally in the sidewall, best seen in Figures 1 and 2B, and the sleeve comprising a connector for releasably attaching the sleeve to a biopsy device comprising the tissue piercing element, best seen in Figure 4, wherein the connector is defined as the end portion of the sleeve by

thumbwheel 32 at which point said tissue piercing element 72, 44 is insertedly attached to the sleeve, also shown in Figure 1;

at least two electrodes (20) disposed on the sleeve, best seen in Figure 2B (left and right) wherein the at least two electrodes are capable of and thus adapted for providing coagulation (¶0030).

5. However, Wardle et al do not disclose the electrodes disposed such that at least a portion of each electrode is positioned proximally of the a distal most portion of the tissue receiving opening and wherein at least a portion of each electrode is positioned distally of a proximal most portion of the tissue receiving opening. Truckai et al disclose an analogous biopsy device comprising an electrode 196 disposed on an outer sleeve 110A such that at least a portion of the electrode is positioned proximally of the a distal most portion of a tissue receiving opening and wherein at least a portion of the electrode is positioned distally of a proximal most portion of the tissue receiving opening, best seen in Figure 7. Shadduck teaches an analogous sleeve comprising at least two electrodes 45a, 45b disposed on the sleeve 305 such that at least a portion of each electrode is positioned proximally of the a distal most portion of a tissue receiving opening and wherein at least a portion of each electrode is positioned distally of a proximal most portion of the tissue receiving opening, best seen in Figure 13A.

6. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the configuration of the electrodes of Wardle et al such that the at least two electrodes are disposed on the sleeve in the manner above as taught by Truckai et al or Shadduck as an equally as effective configuration to achieve the predictable result of proper biopsy of tissue.

7. In regards to **Claim 5**, Wardle et al and Truckai et al or Shadduck disclose first and second electrodes (20) associated with the edges of the tissue receiving opening (22).

8. In regards to **Claim 34**, Wardle et al disclose a biopsy for obtaining a tissue sample at a sample site within a patient, the biopsy device comprising:

a hollow tissue piercing member (14) having a tissue piercing distal end (¶0030) and a tissue receiving port (22, 26) spaced proximally from the tissue piercing distal end, the hollow tissue piercing member insertable in a tissue mass within a patient, best seen in Figure 1 and 2B;

a hollow cutter (72, 44) translatable within the hollow tissue piercing member for severing tissue received in the tissue receiving port at a sample site within the tissue mass, best seen in Figure 4;

at least one electrode (20) disposed outwardly of the hollow tissue piercing member, the at least one electrode capable of and thus adapted to provide coagulation at the sample site after a tissue sample is severed by the cutter.

9. However, Wardle et al do not disclose the electrode disposed such that at least a portion of the electrode is positioned proximally of the a distal most portion of the tissue receiving opening and wherein at least a portion of the electrode is positioned distally of a proximal most portion of the tissue receiving opening. Truckai et al disclose an analogous biopsy device comprising an electrode 196 disposed on an outer sleeve 110A such that at least a portion of the electrode is positioned proximally of the a distal most portion of a tissue receiving opening and wherein at least a portion of the electrode is positioned distally of a proximal most portion of the tissue receiving opening, best seen in Figure 7. Shadduck teaches an analogous sleeve

comprising at least two electrodes 45a, 45b disposed on the sleeve 305 such that at least a portion of each electrode is positioned proximally of the a distal most portion of a tissue receiving opening and wherein at least a portion of each electrode is positioned distally of a proximal most portion of the tissue receiving opening, best seen in Figure 13A.

10. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the configuration of the electrodes of Wardle et al such that the at least one electrode is disposed on the sleeve in the manner above as taught by Truckai et al or Shadduck as an equally as effective configuration to achieve the predictable result of proper biopsy of tissue.

11. **Claims 21-25, and 27-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle et al in view of Shadduck (US Pat No. 6740082).

12. In regards to **Claim 21**, Wardle et al disclose a biopsy device comprising:

a hollow sleeve (14) comprising a proximal end, a distal end, a unitary sidewall extending from the distal end to the proximal end, best seen in Figure 2B, and a lateral opening (22, 26) formed through a portion the unitary sidewall, wherein the lateral opening is configured to receive tissue, wherein the sleeve is configured to axially receive a portion of a biopsy probe instrument (44), and the sleeve comprising a connector for releasably attaching the sleeve to the biopsy probe instrument best seen in Figure 4, wherein the connector is defined as the end portion of the sleeve by thumbwheel 32 at which point said biopsy probe instrument is insertedly attached to the sleeve, also shown in Figure 1;

at least one electrode (20) disposed on an outer surface of the sleeve, best seen in Figure

2B.

13. However, Wardle et al do not disclose said at least one electrode disposed proximally of a distal most portion of the lateral opening. Shadduck discloses an analogous sleeve comprising electrodes (45a-b) disposed proximally of a distal most portion of a lateral opening (76), as an effective configuration for the desired tissue contact, best seen in Figure 6B. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the positioning of the electrode of Wardle et al such that said electrode is disposed proximally of a distal most portion of the lateral opening, as taught by Shadduck, to produce an effective electrode configuration that enhances tissue contact to achieve the predictable result of proper tissue biopsy.

14. In regards to **Claim 22**, Wardle et al disclose the lateral opening (22) is located proximal of the distal end of the sleeve, wherein a portion of the sleeve separates the lateral opening from the distal end of the sleeve, best seen in Figure 2B.

15. In regards to **Claim 23**, Wardle et al disclose a portion of the sidewall extends unitarily from the proximal end of the sleeve to the distal end of the sleeve, best seen in Figure 2B.

16. In regards to **Claim 24**, Wardle et al disclose a connector operable to selectively couple the sleeve with the biopsy probe instrument, best seen in Figure 4.

17. In regards to **Claim 25**, Wardle et al disclose the sleeve (14) has an open distal end (22, 26), which is an opening at the distal end, wherein the sleeve is configured to axially receive a biopsy probe (44) having a distal tip (72) for penetrating tissue, and wherein the sleeve is

configured such that the distal tip of a biopsy probe extends distally from the open distal end of the sleeve when the sleeve is disposed axially over the biopsy probe, best seen in Figures 2-3.

18. In regards to **Claim 27**, Wardle et al disclose the biopsy probe instrument is configured to communicate electrical signals to the electrodes (20) when the sleeve (14) is coupled with the biopsy probe instrument (¶0034-0035).

19. In regards to **Claim 28**, Wardle et al disclose the electrodes (20) are configured and capable to receive communication of electrical signals for a power source independent of the biopsy probe instrument.

20. In regards to **Claim 29**, Wardle et al in combination with Shadduck disclose first and second electrodes positioned along opposites of the lateral opening (22, 26), wherein such variable positioning is obvious to one of ordinary skill in the art, such as that shown in Shadduck Figure 6A.

21. In regards to **Claim 30**, Wardle et al in combination with Shadduck disclose the one or more electrodes comprises an annular electrode positioned at the distal end of the sleeve (14).

22. In regards to **Claim 31**, Wardle et al in combination with Shadduck disclose the one or more electrodes comprises a pair of electrodes separated by an electrode gap, best seen in Figure 6B (Shadduck).

23. In regards to **Claim 32**, Wardle et al disclose the distal end of the sleeve (14) is open (22, 26), wherein there is an opening at the distal end of the sleeve, best seen in Figure 2B.

24. In regards to **Claim 33**, Wardle et al in combination with Shadduck disclose two electrodes, each electrode extending lengthwise in a direction parallel to the longitudinal axis of

the sleeve, and at least a portion of each electrode disposed proximally of a distal most portion of the lateral opening, best seen in Figure 6B (Shadduck).

25. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle et al and Truckai et al or Shadduck in view of Burbank et al (US Pat No. 6540695) and Russell et al (US Pat No. 6500144).

26. Wardle et al and Truckai et al or Shadduck disclose at least two electrodes (20) disposed on an outer surface of the sleeve (14) but are silent as to the dimensions of the electrodes (20). Burbank et al teach electrodes (18), best seen in Figure 1, with a width dimension of between about 3 mm and about 8 mm (Col.11: 58-67). Russell et al teach electrodes (20), best seen in Figure 1, with a length dimension of between about 20 mm and about 40 mm (Col.7: 4-15) as effective sizes for the desired tissue application within the body. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the at least two electrodes of Wardle et al and Truckai et al or Shadduck with a width of about 3mm – 8 mm and a length of about 20 mm – 40 mm, as taught by Burbank et al and Russell et al respectively, to dimension the electrodes at an appropriate size for the desired tissue application.

27. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle et al in view of Shadduck, further in view of Burbank et al (US Pat No. 5526822).

28. Wardle et al in combination with Shadduck disclose the sleeve (14) with a lateral opening (22, 26) for tissue communication and a biopsy probe instrument (44) but do not disclose said biopsy probe instrument with a tissue receiving window. Burbank et al disclose an analogous

biopsy probe instrument (468) with a tissue receiving window (476) disposed within an analogous sleeve (444) also with a lateral opening (446), best seen in Figure 14A, wherein when the sleeve is coupled with the biopsy probe instrument, the sleeve is configured such that the lateral opening permits communication of tissue through the lateral opening of the sleeve and through the tissue receiving window of the biopsy probe instrument (Col.18: 53-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the biopsy probe instrument of Wardle et al as modified by Shadduck to include a tissue receiving window, as taught by Burbank et al, such that when said biopsy probe instrument is coupled to the sleeve the lateral opening of the sleeve enables communication of tissue through the lateral opening and through the tissue receiving port to ensure the prolapse and subsequent effective capture of the tissue.

Response to Arguments

29. Applicant's amendments have overcome the previous §102 rejections.

30. Applicant's arguments filed 4/13/2009 regarding the §103 rejections have been fully considered but they are not persuasive. As elaborated above, Wardle et al teach the sleeve comprising a connector for releasably attaching the sleeve to the biopsy probe instrument best seen in Figure 4, wherein the connector is defined as the end portion of the sleeve by thumbwheel 32 at which point said biopsy probe instrument is insertedly attached to the sleeve, also shown in Figure 1. It is noted that the claims do not recite any specific structure for said connector, which is simply defined as "a thing that connects" (www.dictionary.com).

31. Applicant contends that the modification of Wardle et al with Truckai et al or Shadduck would be counter to the teachings of Wardle et al because Wardle et al teach "distal tip cutter 20" used for "opening up a path through which distal portion 18 of shaft 14 may be inserted." However, it is noted that Wardle et al merely disclose "distal" tip cutter 20, which does not necessarily require said cutter to be disposed at the distal*most* position. In fact, Wardle et al explicitly teach that "distal tip cutter 20 is preferably spaced away from the shaft distal tip 16" see ¶0030 line 11-12. Furthermore, it s noted that the modification of Wardle et al to place the electrodes in the manner elaborated above would not prevent use of said electrodes to "open up a path for the distal portion of shaft 14" considering that the electrodes are still disposed in relatively the same distal position of the sleeve and would thus still function as such.

32. Therefore, it is maintained that the combination of Wardle et al with Truckai et al or Shadduck to modify the positioning of the electrodes is not only proper but also highly motivated by the simple substitution of one known configuration of electrodes for another known configuration which would have been obvious to one of ordinary skill in the art by yielding predictable results to one skilled in the art at the time of the invention.

33. Applicant is reminded that for a proper §103 rejection, "There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). "There is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). For example, motivation to combine prior art references may exist in the nature of

the problem to be solved (Ruiz at 1276, 69 USPQ2d at 1690) or the knowledge of one of ordinary skill in the art (National Steel Car v. Canadian Pacific Railway Ltd., 357 F.3d 1319, 1338, 69 USPQ2d 1641, 1656 (Fed. Cir. 2004))." See MPEP 2143.01. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA) 1969.

34. Furthermore, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736